

FEB 12 2004

## 510(k) Summary per 21 CFR §807.92

<b>Submitter's Name and Address</b>	Boston Scientific Corporation (BSC) Two Scimed Place Maple Grove, MN 55311
<b>Contact Name and Information</b>	Anne V. Rossi Specialist, Regulatory Affairs Phone: 763-494-2827 Fax: 763-494-2222 e-mail: Anne.Rossi@bsci.com
<b>Date Prepared</b>	January 21, 2004
<b>Proprietary Name(s)</b>	IQ™ Guide Wire
<b>Common Name</b>	Catheter Guide Wire
<b>Product Code</b>	74DQX
<b>Classification of Device</b>	Class II, 21 CFR Part 870.1330
<b>Predicate Device</b>	IQ™ Hydrophilic Guide Wire      K032183      August 01, 2003
<b>Device Description</b>	<p>The IQ™ Guide Wires are silicone-coated, steerable, spring-coil guide wires available in a nominal diameter of 0.014 inches (0,36 mm) and nominal lengths of 185 and 300 centimeters with Brachial and Femoral marks at 90cm and 100cm respectively. The tip will have Floppy flexibility, while the rail will offer Moderate Support (MS). The distal two centimeters of all models are radiopaque and available in either a straight shapeable or a pre-formed J-Tip. The IQ™ Guide Wires will be available with and without a lesion length marker system. The 185-centimeter version is designed with a proximal extension section that allows connection to the AddWire™ Extension Wire.</p>

<b>Intended Use of Device</b>	<p>The IQ™ Guide Wires are intended to facilitate the placement and exchange of balloon dilatation catheters or other therapeutic devices during PTCA or PTA or other intravascular interventional procedures. The IQ™ Guide Wires are not intended for use in the cerebral vasculature. The devices are provided non-pyrogenic, sterile, and intended for one procedure only.</p>
<b>Technological Characteristics</b>	<p>The IQ™ Guide Wires utilize similar materials and methods of construction as the IQ™ Hydrophilic Guide Wires (K032183, August 01, 2003). The main differences in construction are the full-length outer spring coil with an inner coil instead of a spring tip and polymer sleeve, and silicone coating instead of hydrophilic coating. The IQ™ Marker version also has marker coils, which the IQ™ Hydrophilic does not.</p>
<b>Non-Clinical Test Summary</b>	<p>Testing and evaluation of the IQ™ Guide Wires included torque response, tip prolapse, tip shapeability, radiopacity, marker location, lubricity, coating adherence/presence, tensile and shear, combined load, visual inspection, device compatibility, biocompatibility, and product shelf-life.</p> <p>Test results verified that the IQ™ Guide Wires met all of the minimum requirements and are adequate for their intended use.</p> <p>The IQ™ Guide Wires are considered substantially equivalent to guide wires currently marketed by Boston Scientific based on a comparison of intended use, design and the results of <i>in vitro</i> testing and evaluation.</p>



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 12 2004

Boston Scientific Corporation  
Ms. Anne V. Rossi  
Regulatory Affairs Specialist  
Two Scimed Place  
Maple Grove, MN 55311

Re: K040140  
Trade/Device Name: IQ™ Guide Wire  
Regulation Number: 21 CFR 870.1330  
Regulation Name: Catheter Guide Wire  
Regulatory Class: Class II  
Product Code: DQX  
Dated: January 21, 2004  
Received: January 22, 2004

Dear Ms. Rossi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

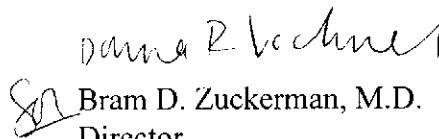
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

  
Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K040140

Device Name: IQ™ Guide Wire

Indications For Use:

The IQ™ Guide Wires are intended to facilitate the placement of balloon dilatation catheters or other therapeutic devices during PTCA, PTA, or other intravascular interventional procedures.

The IQ™ Guide Wires are not intended for use in the cerebral vasculature.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachner  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K040140

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